User's Instructions for the TBR® Prosthetic Products

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This document can be provided in printed paper form at no additional cost within 7 days of request.
Content (non sterile): TBR® prosthetic product (see labelling).
For the prosthetic products that are single use, the following symbol appears on the labelling.

CAUTION

1. For USA: US Federal law restricts this device to sale by or on the order of a dentist or a physician.
2. The TBR® dental implant system must only be used by dental surgeon, stomatologists, maxillofacial surgeons or especially trained surgeons.
3. The TBR® dental implant and prosthetic elements require the specific use of instruments as well as a strict respect of the user's instructions.
4. Any adjustment shall be considered as an alteration of the characteristics and the performances of the TBR® products that may compromise the patients' safety. Therefore, it may void the guarantee and cancel the responsibility of the manufacturer.
5. In order to guarantee the sterility and the cleanliness of the products, the implantable TBR® prosthetic products are single-use. Their re-use, even if resterilized, can generate implant loss, bioincompatibility, permanent tissue lesions and can strongly increase infectious risks (conventional and unconventional).
6. In case of malfunction, inform the manufacturer.

The manufacturer assumes no responsibility if these conditions are not respected.

INDICATIONS

The TBR® prosthesis is designed to be set on TBR® implants that are placed in the bone of the upper or lower jaw arches of partially or totally edentate patients in order to provide support for prosthetic devices in the following cases: unitary edentulousness, insert edentulousness, terminal edentulousness, total edentulousness, stabilization of an overdenture. The bone volume and quality must be sufficient to bear dental implants.

CONTRAINDICATIONS

General contraindications,

Absolute and definitive:

- cardiovascular disorders, coronary insufficiency, bacterial endocarditis, high blood pressure, blood abnormalities: patient on anticoagulants, patient who had a vascular accident,
- immunodeficiency, viral infection (H.I.V seropositivity, A.I.D.S., hepatitis B, C, …), hypersensitivity to Titanium (rare),
- bone disorders, unfavorable bone anatomy, cancers, radiotherapy of the cervico-facial region,
- smoking, alcoholism, drug abuse, mild psychological disorders, psychological problems,
- insulin-dependent diabetes, uncontrolled mature-onset diabetes, on bisphosphonate medication (past or ongoing)
- parafunction, bruxism, periodontal disease.

Absolute and temporary:

- pregnancy, breast feeding, children must have reached bone maturity,
- situations subjected to pressure variations (plane, mountains, scuba diving, etc.) after an implant setting near the maxillary sinuses.

Local contraindications:

- insufficient bone volume or residual roots,
- benign or malignant tumor close to or at the implant site,
- poor oral hygiene, residual infection or cyst,
- prosthetic difficulties (axis, emergence, usable prosthetic space insufficient or incompatible),
- unstabilized periodontal problems,
- low motivation of the patient or unrealistic patient expectations.

This list of contraindications cannot be exhaustive. Before any implant treatment the patient's general health must be clearly established in agreement with the general practitioner.

RISKS - SPECIAL PRECAUTIONS - WARNING

Risks are associated with oral surgery in general (local or general anesthetic risks, hemorrhage, infection, endocarditis, etc.). Perfect conditions of asepsis and sterility of the material are also essential to see this operation through.

The eventual complications can be:

- chronic pain associated with the implant, parasthesia,
- bone loss of the maxillary or mandibular ridge crest, fractures: bone, implant, prosthesis
- oral-antral or oral-nasal communication,

- consequences on adjacent or opposing teeth, aesthetic problems.

Warning

Patients must be informed that:

1. **In the case of complication, the practitioner must be contacted immediately.**
2. **Metal implants and prostheses may alter the potential diagnostic of a magnetic resonance imagery examination.**
3. **A rigorous and non-traumatic hygiene of the patient is recommended as well as regular dental consultations.**
4. **Drug prescriptions that are eventually implemented by the practitioner must be respected.**

TBR® PROSTHETIC PROTOCOL:

(For more details on the products and their references, see the prosthetic catalog.)

In order to meet with the expectations of every patient, the TBR® System offers multiple choices of different abutments, heights, angulations, shapes, types and functions. The complete anamnesis of the patient, clinical examinations, biological and radiological results, the patient's expectations, are really important elements that will help the practitioner to determine the prosthetic project and to set up the implantary treatment plan.

The examination of the bone quantity and quality, mucous thickness and the prosthetic useable space, will ensure to choose the prosthetic pillar from its characteristics for the prosthesis realization. In order to do so, the healing screws (and/or the screw for the shoulder height selection) help with the evaluation of the gum thickness after healing and facilitate the prosthetic pillar choice.

The implant exposition, for the buried implants (Bone Level), is a crucial moment for the implantary therapy, because if the primary healing depends on the surgical act, the secondary healing will depend on the prosthetic stage. During the second surgical stage, the implant cover screw is taken out and replaced by a transgingival healing screw (different heights and diameters depending on the clinical case). It will allow the soft tissue healing. After an average waiting period of 2 to 4 weeks, the final prosthetic pillar will be mounted in the implant.

In the case of Soft Tissue Level implants, the transgingival zirconia ring, that surrounds the implant collar, allows the gum healing as soon as the implant is set (first-line healing for the bone and the soft tissue.

The transgingival healing screws will be chosen depending on the gum and on the prosthetic emergence profile wanted by the practitioner (normal, wide, switching platform).

The prosthetic components of the TBR® System allow a great versatility for the reconstructions:

- Fixed cemented prosthesis,
- Fixed detachable prosthesis,
- Stabilization of removable prosthesis.

For the implants with a morse tapper connection and for the implants with an internal octagon, some prosthetic pieces (such as the cover screws, the healing screws, the transfers and the implant analogs) are colorized depending on the implant type (Bone or Soft Tissue Level) and on the diameter. This color code helps with the recognition of TBR® products.

I. THE LABORATORY TRANSFER TECHNIQUE:

It is the trustworthy transfer of the clinical situation to the laboratory where the prosthetic handlings will be realized with the greatest comfort.

There is one impression abutment (transfer for each impression technique, each implant diameter and each implant system.

There is one implant analog for each type of prosthetic pillar, each implant diameter and each implant system.

An indexation system allows you to know the exact position of the polygonal implant connection.

When the Platform Switching healing screw is used, a specific Platform Switching transfer must be used.

I.1. INDIRECT TECHNIQUE WITH TRANSFERS REPOSITIONING

It is the most commonly used technique.

I.1.1. Material:

The impression abutment (transfer): It is made of a titanium alloy, with an octagonal or hexagonal connection and a double flat for the antirotational blockage of the pillar in the impression. This double flat defines indeed an angle that will allow the repositioning of the transfer in the impression.

The transfer screw: It is made of titanium alloy. It goes through the transfer in order to be screwed onto the implant. On the screw's head, there is a hexagonal housing for the use of the hexagonal screwdriver.

The implant analog: It is made of titanium alloy. It is a trustworthy replica of the implant connection, so that the prosthetic pieces will perfectly fit and can be prepared at the laboratory.

I.1.2. In the patient's mouth:

After the removal of the cover screw (for the Soft Tissue Level implant) or the removal of the healing screw (for the Bone Level implant), the transfers are set on every implant. They must perfectly fit into the implant connection and the screwing must complete. A radiographical check-up is needed to make sure that the transfer is perfectly set into the implant. The hexagonal housing on the screw head must be filled in (pink wax, cotton, etc.) in order to prevent that the impression material fills it. The impression is then realized with commonly used material (silicone), with a double mix and with a dental impression tray. After the removal of the impression, the transfers that are still screwed on the implants are unscrewed and screwed back on the implant analogs. This set is then carefully replaced in the impression. The reproduction in the laboratory of the clinical situation in the mouth is very reliable; it allows an accurate reproduction of the implant connection, of the thread position and of the implant axis.

I.1.3. In the laboratory:

It is possible to make a false gum: the impression with the transfer and the implant analog are coated around the areas of the implants emergence with a separating veneer. When the veneer is dry, an impression material (light silicone) is injected around the transfers' emergence, on a layer of 2 to 5 mm, in order to create the false gum.

Impression cast: A plaster impression is casted in a conventional way (after the setting of the light material in case of a false gum).

I.1.4. Results:
The demoulding will give a plaster model with a soft silicon part (around the areas of the implants emergence) that is unmountable and that will duplicate the soft tissue around the implant emergence. This technique will give us precise information about the depth of the peri-implantary sulci. This unmountable area with silicone helps the prosthetist to know the cervical limit of the gum in order to adjust the pillars and the prostheses. The models are then fixed on an articulated jaw.

I.2. DIRECT TECHNIQUE.
This technique is recommended when the implants do not have a marked parallelism (more than 25°).
The clinical approach is the same as the previous one except that the transfers are distinct (direct transfer) and designed for this technique.
I.2.1. Material:
The impression abutment (transfer): It is made of a titanium alloy; it has a hexagonal or octagonal connection and 4-sided geometry (two stacked squares), a groove at half-way (between the two squares) that will vertically allow the blockage of the transfer in the impression.
The transfer screw: It is made of titanium alloy. It goes through the transfer in order to be screwed onto the implant. On the screw's head, there is a hexagonal housing for the use of the hexagonal screwdriver.
The implant analog: It is made of titanium alloy. It is a trustworthy replica of the implant connection, so that the prosthetic pieces will perfectly fit and can be prepared at the laboratory.
I.2.2. In the patient's mouth:
This technique will use an individual dental impression tray that has been beforehand cut around the emergences areas of the transfers. Thus before the setting of the impression material and before the removal of the individual dental impression tray, you will have to unscrew the transfer screw through the window of the impression tray. As the transfer is not screwed on the implant anymore, it will be removed with the impression. So you will only have the put the transfer that is stuck inside the impression on the implant analog.
I.2.3. In the laboratory: *See the previous method.*

I.3. SWISSCLIP TECHNIQUE.
This technique is recommended for clinical cases with 1 to 3 implants. The ergonomics and the accuracy of the products have been specially designed for the practitioner and the patient's comfort.
The clinical approach is the same as the previous one except that the transfers are distinct (SwissClip transfer) and designed for this technique.
I.3.1. Material:
The impression abutment (transfer): It is made of a titanium alloy; it has a hexagonal or octagonal connection and 4-sided geometry (two stacked squares), a groove at half-way (between the two squares) that will vertically allow the blockage of the transfer in the impression. There is a second groove that will receive the PEEK ring for the clamping of the transfer in the implant. There is no transfer screw.
The implant analog: It is made of titanium alloy. It is a trustworthy replica of the implant connection, so that the prosthetic pieces will perfectly fit and can be prepared at the laboratory.
I.3.2. In the patient's mouth:
The impression is made with commonly used material (silicone) in a double mix and with a dental impression tray. Thus after the setting of the impression material, the dental impression tray will be removed. As the transfer is only clamped on the implant, it will also be removed with the impression tray. Then the transfer will stay in the impression and be put on the implant analog.
I.3.3. In the laboratory: *See the previous method.*

II. FIXED CEMENTED PROSTHESIS:
The TBR® system has different prosthetic possibilities for the fixed cemented prosthesis.
The prosthesis depends on:
- The type of implant that has been set: octagonal connection, M, etc.
- The implants diameter: 3.2 - 3.5 – 3.9 – 4 – 4.7 - 5 mm,
- The angulation: 0° - 15° - 25°
- The shape (Platform Switching) and the shoulder height: 0 – 0.7 – 1.5 – 2 – 3 – 4 – 5 mm.

II.1. TEMPORARY ABUTMENTS
The temporary abutments are made of (Poly-ether-ether-ketone) and are screw-retained by a titanium screw.
The setting of these abutments in the oral cavity must not exceed 30 days while waiting for the definitive abutments (titanium abutment, zirconia abutment, etc.).
The prosthetic protocol for the setting of these abutments is the same as the one for the titanium abutments (see chapter II.2).

II.2. SCREW-RETAINED TITANIUM ABUTMENTS
The choice of the abutment (shoulder height, angulation, etc.) will depend on the connection type, the implant diameter, the gum quantity and quality and the mergence profile whished by the practitioner.
After the removal of the transgingival healing screw, the screw is mounted on the screwdriver and it goes through the titanium abutment. All these products are then placed in the patient's mouth. First the screwing is partially realized in order to have enough space for the fitting of the pillar into the implant for the choice of the ideal axis. At this stage, the abutment height and axis are checked. If an adjustment is needed, the abutment should be taken out in order to make all the alterations out of the mouth.
When the abutment is adjusted and the ideal position has been spotted, it is put back in the mouth and screwed in the implant. It is needed to apply a torque of 20 to 30 N.cm in order to activate the morse tapper of the screws and abutments (this torque depends on the bone quality, the implant length and the osseointegration period). A torque wrench can be found in the surgical kit and in the prosthetic kit and it allows the application of an accurate torque. A radiographical check-up will ensure that the abutment is perfectly screwed. It is important that the abutment has to be correctly connected; the base of the abutment must totally cover the implant head.

The head of the abutment screw must always be protected (with some gutta percha, cotton, etc.) in order to help with the dismantling of the abutment if needed. The hollow housing of the abutment is filled by a composite, IRM, etc.
At this point, the prosthetic stage becomes conventional and the impression will be classical.

II.3. Castable Abutments with or without an Overflow Ring

The TBR® system offers two types of castable abutment: a screw-retained castable abutment and a screw-retained castable abutment with an overflow ring.
Note: Castable abutments with a post are also available.

Screw-retained castable abutment:

It is a hollow tube connected to the implant with an octagonal or a rounded base. It is retained with a titanium screw. These castable abutments are a solution for the clinical cases where the standard abutment cannot be used. Thus the practitioner and the laboratory technician will build the kind of pillar with the wanted shape and angulation. These abutments are made of 100% castable material with a faithful reproduction.

Castable abutment with an overflow ring:

It has two parts:

- A ring made of precious metal (for the flat connections only) or non-precious metal that will be a faithful reproduction of the male part that will be inserted in the implant.
- A castable sheath.

The ring made of non-precious metal can have different types (depending on the connection type):

- With a hexagonal base,
- With a round base,
- With a shoulder height of 0,7 mm,
- With no shoulder,
- With no shoulder and a round base.

All the pieces are screw-retained in the implant body thanks to a titanium screw.
There is one ring for each connection type and implant diameter. The indication is the same as the one for the castable abutment; the overflow ring only guarantees that it will fit better in the connection. The implementation will be the same as the one for the castable abutment.

II.4. Screw-Retained Abutment Zenith (for the octagonal connection only)

This is a zirconia abutment screw-retained with a titanium screw. The advantage of these all-ceramics crowns is to be light permeable like the natural teeth.
The setting of the Zenith abutment is the same as the one for the classical titanium abutment (see chapter II.2).
Some additional precautions must be taken during the alterations of these abutments:

- Use a water-cooled diamond milling cutter to make the alterations.
- Round off edges before setting the abutment in the patient's mouth.
- Do not have a too thin wall for the Zenith abutment (leave at least a thickness of 0.5 mm).

III. Fixed Detachable Prosthesis:

III.1. Straight Titanium Base (Conical Abutment)

The choice is determined by:

- The implant system: octagonal connection, M, etc.
- The implant diameters: 3.2 - 3.5 - 3.9 – 4 - 4.7 - 5
- The depth of the peri-implantary sulcus and the useable prosthetic height.

After the removal of the transgingival healing screws (bone level implants), the bases (conical abutments) are screwed on the implants. The specific transfers are placed on these conical abutments. The impression taking and the transfer of this situation at the laboratory has been previously described.
After the impression taking, the bases stay in the patient's mouth and are covered by a protection cap while waiting for the prosthetic setting.
After the model casting, the prosthetist has replicas (analog of the implant with the conical abutment) for the laboratory stage. The crowns or the bridge are made from the castable pillars that are screwed on the replicas. The height and the angulation of these castable pillars are adapted to the useable prosthetic space and by respecting the occlusion criteria.
For the one-stage technique (soft tissue level implants), the technique is the same one but with the use of specific conical abutments (see the products catalog for the references choice). Screw the prosthesis using the remaining screw. When you will be sure of the positioning and for final screwing step, tighten the screw with the torque wrench and its tip. (Torque strength: 20 to 30 N.cm depending on the implant diameter and length, on the bone quality and on the healing period.)
The conical abutments are used for the multiple prosthetic restorations. Indeed a screw-retained multi-elements bridge will need a perfect parallelism of the implants. However it is clinically very hard to have an ideal parallelism, even if you can be close to this situation, the bioshape of the conical pillar will help with the axis and then to screw-retain the prosthesis without excessive mechanical stress.

III.2. Angulated Titanium Base (Angulated Conical Abutment)

The protocol for the use of the angulated conical abutment is:

- Orientate and insert the lower part of the angulated conical abutment in the implant connection in the wanted position.
- Insert and set the screw with the smaller conical head by using the screwdriver. When you will be sure of the positioning and at a final screwing step, tighten the screw with the torque wrench and its tip with a torque of 20 to 30 N.cm (it will depend on the implant diameter and length, on the bone quality and on the healing period).

- With the help of the conical abutment screwtool, manually screw the conical head abutment. We advise you to coat the external thread with anaerobic glue like CEKABOND. In case of an abutment setting while waiting for the gingival waiting, put a conical abutment protection cap on the abutment.
- Screw the prosthesis using the remaining screw. When you will be sure of the positioning and for the final screwing step, tighten the screw with the torque wrench and its tip with a torque of 20 to 30 N.cm (it will depend on the implant diameter and length, on the bone quality and on the healing period).

Note: When the castable pillar with a round base is used:
It is possible to realize a unitary crown or a screwed small bridge (if the implants are perfectly parallel). To do so, the castable pillar will be altered and adjusted but without any alteration to part that goes inside the implant, by shaping the future crown and by carefully handling the screw shank.

III.3. Definitive and Temporary Sheath for Conical Abutments

The indications of these temporary and definitive conical sheaths are for the immediate or definitive complete fixed detachable prostheses. They replace the castable abutment. When the bridge or the total prosthesis is done, it must be glued to the resin with or without an access for the screw in the shank.

III.4. Specific Transfers

There are also specific transfers for this type of prosthesis and it depends on the used impression technique (direct or indirect). The protocol will be the same as in chapter I, except that the transfer is set directly on the titanium base and not on the implant.

IV. Stabilization of Removable Prosthesis :

There are three prosthetic options: bar-borne restorations, spherical attachment and Locator® system.

IV.1. Bar-borne Restorations

This anchoring principle allows the implants to be linked together. Thus there will be a better resistance to the lateral components applied on the implants by neutralizing them.
The needed elements for the prosthesis on at least 3 implants are:

- conical abutments for fixed prosthesis,
- a castable bar,
- clip,
- a spacer.

After soft tissue healing, remove the transgingival healing screws and build a bar-borne restoration with the direct or indirect technique.
Note: Plan enough space between the bar and the gum (a minimum of 2 mm) in order to have an easy access and a good maintenance.

IV.1.1. Direct technique:

When the healing screws have been removed, dry the interior of the implants and set the conical abutments. The castable sheaths are also positioned and screwed on the conical abutments. The adjustment of the castable sheath height is done directly in the patient's mouth and it will depend on the available prosthetic height. Use a caliper to measure the distance between each pillar in order to cut the appropriate castable bar segments. Coat every bar end with autopolymerizing resin that has a smooth consistency. Put this segment in the patient's mouth after drying the castable sheaths. The bar is put in an ideal position until the polymerization of the resin. You must perform this operation for every bar segment. When the bar has been realized and the resin has polymerized, remove the screws and send the bar directly to the laboratory (with the screws) for the casting. This casting can be done with precious or non-precious metal or with titanium. In the meantime, the conical abutments stay in the patient's mouth and are protected with conical abutment protection caps.
Note: It is also possible to use overflow ring, and in this case, the bar can be casted with palladium gold.
When the bar has been casted in the laboratory, the protection caps are removed; the bar is set and screwed on the conical abutments. When the bar is set in the patient's mouth, the realization of the removable prosthesis can be done in the same way as fixed overdenture prosthesis on Dolder's or Ackermann's bar.
Note: These prostheses must be set on the mucous in a conventional way. Implants and bar have a retention role and not a carrier role. The prosthesis must not touch the bar or the implants. Only the working part of the clips must have a retentive contact with the bar. The clip back must not lean on the bar (use of the spacer at the laboratory).

IV.1.2. Indirect technique: Transfer at the laboratory

After the removal of the healing screws, screw the conical abutments on the implants. Use the impression and transfer technique at the laboratory that has been previously described. The laboratory has the conical abutment replicas. During the laboratory stage, cap protections are screwed on the conical abutments. After the bar casting, the cap protections are removed and the bar is screwed on the implants.

IV.2. Spherical Attachment

The spherical attachment is made of a pillar attachment that is directly screwed on the implant. This pillar depends on:

- the implant system,
- the implant diameter,
- the available prosthetic height.

There also is a female part that can either be a ring with a toroidal joint that crimps the spherical abutment, or a cap that is clipped on the spherical pillar.
It is recommended to use the direct technique with the transfer of the clinical situation at the laboratory. In order to do so, screw the spherical abutment and take its impression. Put the analog assembly (spherical abutment and implant analog) in the impression for the laboratory. Realize the model casting with the false gum technique. The female part is positioned in the basal surface of the prosthesis. The mounting is done in a conventional way.

IV.3. LOCATOR®

IV.3.1. Placement of the Locator® abutment:

1. To select the proper Locator® Abutment, determine the type of implant and the diameter being used. Then measure the tissue thickness from the apical rim of the implant body to the crest of the gingiva at the highest side of the implant site. Choose the corresponding abutment tissue cuff height that exactly equals the tissue measurement, or is the next closest higher size available. The exact tissue cuff height of Locator® abutment will position the proper 1.5mm of working attachment above the surrounding gingival level (which should not be submerged below the tissue).
2. After the secondary gingival healing period is complete, remove the healing cuff according to the usual instructions.
3. It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the Locator® Abutment.
4. A manual screwdriver has been created in order to screw the Locator® Abutment in the internal part of the implant.
5. The torque wrench with the help of the special triangle tip will finalize the tightening of the Locator® Abutment in order to prevent screw loosening. The recommended torque strength is from 20 to 30 N.cm depending on the implant diameter and length, on the bone quality and on the healing period

IV.3.2. Angle Measurement of a Divergent Implant:

1. Place the Locator® abutment into the implant.
2. Then snap a Parallel Post onto it.
3. Use the Angle Measurement Guide behind the Parallel Post to determine the angle of the implant.
4. Choose the final Locator® nylon male retention liner based upon the determined angle measurement of each implant. If the divergence of an implant is less than 10 degrees (i.e. 20 degrees between the two implants), use one of the Locator® Replacement Males (clear = 2,26 kg, pink = 1,36 kg, and blue = 0,68 kg.). If the divergence of any implant is between 10 degrees and 20 degrees (i.e. 20 to 40 degrees between the two implants), then use one of the Locator® Replacement Males (green = 1,81 kg. and red = 0,45 kg.).
5. Follow the steps in Section IV.3.3. Locator® Male Placement by the Dentist for chairside placement of the Locator® Male, or the steps in Section IV.3.4. Locator® Male Placement by the Laboratory for indirect placement of the Locator® Male.

IV.3.3. Locator® Male Placement by the Dentist:

1. Insertion of the proper Locator® Abutment at tissue level must be completed before beginning the procedure for placement of the Locator® Male.
2. Place a White Block-Out Spacer over the head of each Locator® Abutment. The spacer is used to block out the area immediately surrounding the abutment. The space created will allow the full resilient function of the pivoting metal denture cap over the Locator® Male.
Note: If the White Block-Out Spacer does not completely fill the space between the tissue and the metal denture cap, it is necessary to block out any remaining undercuts to prevent the added acrylic resin from locking the denture onto the abutment. This can be accomplished by stacking more Block-Out Spacers.
3. Insert a Locator® Cap with Black Processing Male into each Locator® Abutment, leaving the White Block-Out spacer beneath it. The Black Processing Male will maintain the overdenture in the upper limit of its vertical resiliency during the processing procedure.
4. Prepare a recess in the denture to accommodate the protruding Locator® Male. There must be no contact between the denture and the titanium cap. If the denture rests on the metal cap, excess pressure on the implant will result.
5. Mix a permanent self-curing acrylic and place a small amount in the recess of the denture and around the metal cap of the Processing Cap Male.
6. Insert the denture into position in the oral cavity. Guide the patient into occlusion, maintaining a proper relationship with the opposing arch. Maintain the denture in a passive condition, without compression of the soft tissue, while the acrylic sets. Excessive occlusal pressure during the setting time may cause tissue recoil against the denture base and could contribute to dislodging and wear of the nylon males.
7. After the acrylic resin has cured, remove the denture and discard the white spacer. Use a bur to remove excess acrylic, and polish the denture base before changing to the final male.
8. Use the Locator® Male Removal Tool (attached to the Locator® Core Tool) to remove the Black Processing Male from the metal denture cap. The sharp circular edge on the end of the removal tool should be wedged tightly down into the very bottom of the plastic male so that it will catch the inside of the black plastic insert and pull it at an angle out of the metal housing. To discard the nylon male from the new tip on the Core Tool, point the tool down and away from you and tighten the new Male Removal Tool clockwise back onto the Core Tool. This will activate the removal pin and dislodge the nylon male from the tip end of the Male Removal Tool.
9. The Locator® Male Seating Tool (contained in Locator® Core Tool) is used to firmly push a Locator® Replacement Male into the metal Denture Cap. The replacement male must seat securely into place, level with the rim of the cap.
Note: The Replacement Male will not stay on the tool when it is turned upside down due to the varying sizes of males available. It is best to hold the denture with the base side down and snap the male into the metal denture cap.
10. Instruct the patient in the path of insertion. Have the patient insert and remove the appliance several times.

IV.3.4. Locator® Male Placement by the Laboratory:

1. Insertion of the proper Locator® Abutment at tissue level and with the right connection must be completed before beginning the following impression procedure.
2. Place a Locator® impression on every Locator® Abutment.
3. Take an impression using a firm body impression material, exercising caution not to compress the soft tissue. The Locator® Impression Coping is designed with minimum retention to be picked up with the impression material.
4. Snap a Locator® Female Analog onto each Impression Coping in the impression. The analog female must not fall off when turned upside-down with vibration.

5. Pour the master cast. Upon separation, the Locator® Female Analog is a part of the master cast replicating the position of the Locator® Abutment in the oral cavity.
6. Before waxing and processing the appliance, place a Locator® Cap with Black Processing Male into each Female Analog in the master cast. Make sure the male is fully seated.
7. Set the teeth and wax the appliance. Proceed with the processing technique of your choice through the boil-out step.
8. After the boil-out, remove the Processing Cap Male. Place a White Block-Out Spacer over the head of each Female Analog. The spacer is used to block out the immediate area surrounding the Locator® Abutment. The space created will allow the full resilient function of the pivoting metal denture cap over the Locator® Male.
9. Re-insert the Locator® Black Processing Cap Male into each Female Analog, leaving the White Block-Out Spacer beneath it. The Black Processing Male will maintain the overdenture in the upper limit of its vertical resiliency during the processing procedure.
10. Complete the processing and discard the white spacer. Avoid damage to the final male by polishing the denture base before changing to the final male.
11. Use the Locator® Male Removal Tool attached to the Locator® Core Tool to remove the Black Processing Male from the metal denture cap. The sharp circular edge on the end of the removal tool should be wedged tightly down into the very bottom of the plastic insert so that it will catch the inside of the black plastic insert and pull it at an angle out of the metal housing.
12. The Locator® Male Seating Tool is used to firmly push a Locator® Replacement Male into the empty metal denture cap. The replacement male must seat securely into place, level with the rim of the cap.
Note: The Replacement Male will not stay on the tool when it is turned upside down due to the varying sizes of males available. It is best to hold the denture with the base side down and snap the male into the metal denture cap.

IV.3.5. How to Change the Locator® Male:
The Locator® Core Tool, which contains a Locator® Male Removal Tool and Locator® Male Seating Tool, is used to remove the nylon male from the metal denture cap and replace it with another Locator® Replacement Male.
1. Use the Male Removal Tool attached to the Locator® Core Tool to remove the nylon male from the metal denture cap. The sharp circular edge on the end of the removal tool should be wedged tightly down into the very bottom of the plastic male so that it will catch the inside of the plastic insert and pull it at an angle out of the metal housing.
2. The Male Seating Tool is used to firmly push a Locator® Replacement Male into the empty metal denture cap. The replacement male must seat securely into place, level with the rim of the cap.
Use of multiple Locator® attachments (3 or more) in the same dental arch may require use of the light retention (pink color – 1,36 kg) or super light retention (blue color – 0,68 kg) for easier removal of the prosthesis by the patient.
Note: The retentions change is easier if the metal denture cap is polymerized in the prosthesis. All the operations described previously are done by holding the prosthesis in one hand while the other hand holds the Locator® Core Tool.

IV.3.6. Reline and Rebase:
1. Remove each existing nylon male from its metal denture cap following the steps in the section IV.3.5 How to Change the Locator® Male. Replace them with Black Processing Replacement Males. The built-in spacer of the Black Processing Male will maintain the overdenture in its upper level of vertical resiliency during the reline process.
2. Take a reline impression using the existing overdenture as a tray. The Black Processing Males will engage the Locator® Abutments and hold the prosthesis in place while the impression material sets.
3. When the impression is withdrawn, the Black Processing Replacement Males will remain in the metal denture caps.
4. Snap a Locator® Female Analog onto each Black Processing Cap Male and pour a master model.
5. After processing the reline and polishing the denture base, replace the Black Processing Males with the final Locator® Replacement Males.

V. PROSTHETIC KITS:
There are two prosthetic kits depending on the implant connection: octagonal or morse tapper. They contain all the instruments needed to elaborate the prosthetic project: screwdrivers, tip for contra-angle, tip for torque wrench, extractors for torque wrench (only for the morse tapper prosthetic kit), angulation kit, shoulder height kit, torque wrench, adaptor for torque wrench and conical pillar screwtool.

VI. CAD/CAM:
VI.1. SCANBODY
The Scanbody are digital transfer for the implants. They must be placed on the implants in the patient's mouth (reading with intra-oral camera) or on a plaster cast (reading with a desktop scanner). These products, made from titanium for the part inside the implant and from PEEK for the part outside the implant, ensure the precise spatial repositioning of the implant connection thanks to the specific bioshape that is unique for the PEEK part. Thus it will be possible to realize personalized supra-structures CAD/CAM.

VI.2. CONNECTION BASE
The titanium connection bases are intended to receive a personalized ceramic mesostructure; these products are glued together. These bases can have a polygonal or round connection, adapted to the octagonal and hexagonal morse tapper connections of the TBR® implants. These bases look like a short pillar on which is glued the ceramic supra-structure personalized for the dental arch of the patient.

DISINFECTION, CLEANING AND STERILIZATION
The prosthetic elements and the ancillary used during the prosthesis stage are sold non sterile.

Warning
If the packaging is damaged or soiled, the implant cannot be returned or exchanged by the manufacturer.

Warnings and recommendations for disinfection, cleaning and sterilization

Metallic prosthetic elements and ancillary instruments must be disinfected, cleaned, sterilized by trained and qualified staff. Check for the presence, the cleanliness, the operational state and the qualification (calibration, maintenance, etc.) of all the necessary material before starting the cleaning and sterilization cycle. The handling of contaminated devices must be done by using personal protective equipment (gloves, gowns, glasses, mask, etc. ...). The drying, packaging and sterilization process must be performed in a clean, orderly and clear environment.

Caution:

All the parts to be sterilized require some recommendations for the preservation of their quality. The non-respect of these instructions can alter the lifetime of the devices (corrosion, coloring, deterioration of the marking, premature wear, etc.) and the users and patients safety (contamination):

Point A: Use cleaning / disinfection products adapted to surgical instrumentation and materials they are made of. Do not use products containing chlorine, iodine, phenols, strong acids or alkaline (do not use sodium hypochlorite (bleach), oxalic acid, sodium hydroxide or hydrogen peroxide, or normal saline, beware of the too strongly chlorinated tap water). Avoid any product containing aldehyde because of their ability to bind proteins.

Point B: For the washer-disinfector: Only use agents recommended by the manufacturer and prefer the use of slightly alkaline products (pH between 7 and 10.5).

Point C: For all products and materials (for cleaning / disinfection, washer-disinfector, ultrasound vat, sterilization pouch, autoclave etc.), follow carefully all manufacturer's instructions (dosage, soaking time, temperature etc ...) and expiration dates.

Point D: Avoid as far as possible shocks and contacts with other instruments (deterioration of the surface state, the marking laser and/or the cutting power).

Point E: Please clean products made from the same material in the same container.

Point F: Do not leave contaminated instruments to dry before the cleaning / sterilization cycle.

Before each intervention:

1. As soon as possible after their use (if more than 30 minutes, do not forget to wrap them in a damp cloth to prevent the soiling from drying), the dirty instruments are carried in a suitable container, avoiding shocks, to the area dedicated for the cleaning. They are arranged in a clean and adapted packaging, dismantled if necessary (in the case of the torque wrench) and completely soaked in a freshly prepared disinfecting solution, without any bubble (the use of a system with ultrasounds is also appropriate) (see points A,C, D & E). Rinse thoroughly under running water until the absence of chemical residues on the device.

2. Remove carefully all the post-operative residues (blood, bones ...) on the instruments (use a nylon brush), or inside for products with an internal irrigation or hollow products (thanks to a syringe, e.g. drills, cannula, etc.) by using an alkaline detergent (but not a strong one) or neutral one (see points A, C & E). Rinse thoroughly (preferably use using deionized water for the final rinse).

3. In case of a manual cleaning: Immediately after cleaning, dry all the instruments surfaces with a lint-free clean absorbing paper by scrubbing carefully or with compressed air for medical use (see points C).

In case of a washer-disinfector: Immediately after cleaning, put the instruments in the washer-disinfector avoiding contacts between the devices and start the cycle following the manufacturer's instructions (see points B, C & D).

4. Visually inspect the cleanliness and the absence of humidity or stains on the components and make sure that no deterioration may affect their safety, integrity or functioning. If necessary, repeat the cleaning cycle from the point 2. Reassemble the instruments when needed. Put one or several products in a sterilization pouch, big enough so that no tension is applied on the closure (see point C).

5. Make sure that no corroded elements are inside the type B pressurized steam sterilizer. Sterilize in the autoclave at 134 °C, 18 minutes (see points C & E).

6. Verify the good progress of the cycle, the integrity of the pouches as well as the physico-chemical indicator of sterilization (if necessary, start again the operation from the point 4). Indicate the sterilization date on every pouch (and any information necessary for the traceability) which will then be stored in conditions preserving the products safety and sterility (a clean, dry, safe and stress-free place, at room temperature and out of direct sunlight).

STORAGE – ELIMINATION

Store the implants in their original storage pack, at room temperature, in a dry area (from 10 to 30°C) and protected from any deterioration risk. The products that have to be eliminated are thrown away in sharp disposal containers.

TRACEABILITY

In order to guarantee the security of patients, the practitioner must keep the reference and batch number for all the products that has been set or used. These specifications are stipulated on the adhesive detachable labels on the TBR® products.

We advise to not use any TBR® products when the packaging is damaged or when the label is unreadable.

FORMATION

TBR® Group offers on a regular basis trainings about implantology and about the use of TBR® products.